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Interview Summary

Application No.	Applicant(s)	
09/533,906	Collins et al	
Examiner	Group Art Unit	
Diana Johannsen	1655	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Diana Johannsen*

(2) *Carla Myers*

(3) *Cecilia Tsang*

(4) *Jean B. Fordis*

(5) Norval B. Galloway

(6) David J. Lane

Date of Interview *Jan 16, 2001*

Type: ☐ Telephonic ☒ Personal (copy is given to ☐ applicant ☒ applicant's representative).

by FAX to 202/408-4400

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description:

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: *all pending*

Identification of prior art discussed:

See attachment.

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

See attachment.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendents which would render the claims allowable is available, a summary thereof must be attached.)

1. ☐ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Diana J

1/16/01

DIANA JOHANNSEN
PATENT EXAMINER
ART UNIT 1655

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

Attachment to Interview Summary

Prior art discussed.

PCR Technology (H.A. Erlich, ed., Stockton Press 1989, pp. 1-5), PCR Protocols (M.A. Innis et al, eds., Academic Press 1990, pp. 13-19), Mangiapan et al (J. Clin. Microbiol. 34:1209 [1996]), Hill (IVD Technology 6:36 [2000]), Brown et al (Ann. Rev. Biochem. 43:667 [1974]), Rabinow (Making PCR, Univ. Chicago Press 1996, p. 9), Arsenyan et al (Gene 11:97 [1980]), Boss et al (J. Biol. Chem. 256(24):12958 [1981]), Gaubatz et al (Biochim. Biophys. Acta 825:175 [1985]), Powell et al (Cell 50:831 [1987]).

Comments on discussion.

Ms. Fordis presented an overview of the invention and described advantages provided by target capture that were not appreciated in the art as of the time of filing of the present application (specifically, separation of target molecules from contaminants/inhibitors of amplification), referring to teachings in the Erlich and White references that target purification prior to amplification is unnecessary. Ms. Fordis discussed the 1996 Mangiapan reference, which was cited during the prosecution of the '338 patent and which presents sequence capture PCR as a new development. It was agreed that applicants consider 12/21/1987 to be the priority date to which they are entitled with respect to the pending claims. Ms. Fordis noted that the protest filed in the case ignores problems of sample processing that are discussed in, e.g., the Hill reference.

Ms. Fordis argued that the high levels of amplification and amplification "*in vitro* by an efficient DNA polymerase" discussed on page 687 of the Brown reference were not possible at the time of the Brown reference (1974), and that the Brown reference would have led one to have employed cloning rather than some type of *in vitro* amplification. Dr. Lane noted that, from 1975 to the early 1980's, cloning was the "method of choice" to obtain copies of a nucleic acid target, and Ms. Fordis referred to the Rabinow reference in support of this. Ex. Myers noted that while unexpected results related to improvement of PCR by separation of targets from contaminants were relied upon in the allowance of the '338 patent, the instant specification does not make reference to PCR or to any advantage related to removal of contaminants/inhibitors. Dr. Lane noted that all enzymatic amplification techniques would be subject to inhibitors, although the particular types of inhibitors might vary. Ms. Fordis referred to col 13 of the '338 patent, noting that the invention was described as providing increased sensitivity, and Mr. Galloway noted that a number of types of *in vitro* amplification are disclosed in the specification. In response to a question from Ex. Myers, it was noted by applicants representatives that the advantages provided by removal of inhibitors would be advantageous in both specific and non-specific capture and amplification methods. It was noted that in embodiments in which specific capture probes are employed, one advantage of the present invention is the ability to amplify captured targets either specifically or non-specifically. Ex. Myers inquired as to whether any advantages other that contaminant/inhibitor removal were provided by target capture *per se*. Ex. Johannsen noted that the specification appeared to provide basis for the amendments presented in the reissue

application, and that the specification provided basis for both specific and non-specific amplification of targets subsequent to capture. Ex. Johannsen noted the breadth of the kit claims, and noted that it did not appear that the kit claims had been separately addressed in the '338 application or in the reissue application to date. It was further noted that the kit claims would have to be examined anew, independent of the method claims (i.e., method step limitations cannot be read into the kit claims). The breadth of the term "amplification" was discussed, with Ex.'s Myers and Johannsen noting the breadth of the definition at col 2, and Ms. Fordis arguing that this definition cannot be read alone, and that the totality of the claims and specification (including col 15-16 and examples 4-7) make clear that the term as used in the claims is limited to *in vitro* amplification. Ex. Myers noted that the reissue claims (e.g. claim 41), in reciting the limitation "*in vitro* amplification", might suggested that the independent claims are intended to encompass both *in vivo* and *in vitro* amplification. Ms. Fordis noted that the claims include additional limitations (e.g., to production of a "multitude" of "polynucleotide amplification products"). Ms. Fordis noted that the issue of priority raised in footnote 8 of the protest (and discussed in footnote 19 of the response) relates to a different group of applications and not to the present case. Ms. Fordis briefly discussed the Arsenyan, Boss, Gaubatz, and Powell references, noting that these references do not anticipate the *in vitro* amplification methods of the present invention, as discussed in the response to the protest. Ms. Fordis noted that a supplemental IDS will be submitted by the week of 1/22/01. It was agreed that Ms. Fordis and Ex. Johannsen will be in contact early next week, prior to action on the case by Ex. Johannsen. It was further agreed that

applicants may submit, within the next week or two, additional information/arguments with respect to the new issues raised by Ex.'s Myers and Johannsen prior to action on the reissue application.

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*** TX REPORT ***

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Fax Cover Sheet

Date: 1/17/01

To: Jean Fordis	**From:** Diana Johannsen
Application/Control Number: 09/533,906	**Art Unit:** 1655
Fax No.: 202/408-4400	**Phone No.:** 703/305-0761
Voice No.:	**Return Fax No.:**
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Comments: Interview Summary.

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